

Rec'd PCT/INT 26 MAR 2004

## STERILE AIR TROLLEY

### Field of the Invention

5

The present invention primarily concerns improvements in and relating to sterile air trolleys such as may be required for a range of different uses that require an open-topped sterile work surface, including the holding of pharmaceutical or electronic components or surgical instruments for use during a surgical operation.

10

### Background to the Invention

Sterile air systems are used in a wide range of different applications and correspondingly take a wide range of different forms. As a generality, however, the 15 majority of sterile air systems involve drawing air into a unit through suction by a fan, and then direct the air through a filter, suitably of the type known as a HEPA (high efficiency particulate air) filter, and then ducting the filtered air to the required target zone whether it be a work surface or an entire room.

20 One particular situation in which a supply of sterile air is very important is in the surgical operating theatre of a hospital. When the hospital has extensive financial resources they will seek to condition and sterilise the air supply blown down onto the operating table. However, this is not always financially viable and does not necessarily ensure a sterile air environment in all areas of the theatre. One 25 particular key area in the operating theatre is the area surrounding the surgical tools to be used in the operation. These surgical tools are normally presented to the surgeon on the work surface of an open topped trolley or on a tray having recently been sterilised in an autoclave. Access to these surgical tools must, of course, be unhindered during the operation. However, attempts have been made in the prior 30 art to provide a localised sterile air environment for the surgical instruments. Prior US patents nos. US 4,531,956 and US 4,996,910 detail designs of sterile air trolley for just this purpose and which may also be used for other applications such as providing a low cost sterile area for purposes of pharmaceutical or electronic production where a full clean room is not available, or needs to be supplemented.

35

In those prior sterile air trolleys air is drawn in to a base unit of the trolley by a fan, and driven upwards through filters to a work surface of the trolley. In the case of US 4,531,956, the air exits through the work surface of the trolley, which is formed as a perforated upper face of a hollow platform, the platform also having 5 perforations in its sides and in an overhanging underside of the platform. The filtered air thus passes out from the work surface in substantially all directions to create an envelope of sterile air surrounding the work surface. This envelope of filtered air will, however, be disrupted by the objects placed on the work surface and vulnerable to disturbance in the environment of the trolley, and in practice cannot be 10 relied upon to maintain a sterile environment around the work surface in the run up to and during the course of an operation. A further risk of having airflow upwardly through outlets in the work surface is the entrainment of blood from surgical instruments replaced on the work surface in the airflow as an aerosol.

15 The subsequent US patent, US 4,996,910 seeks to improve on the earlier design and provides a horizontal work station on the top of the trolley having a casing upstanding from one end of the working surface with perforations to direct filtered air outwardly in all directions as well as having deflector plates to deflect bulk air flow from the upstanding casing substantially horizontally across the work surface toward 20 the user. As with the earlier design, the objective is to create a buffer zone of sterile air extending substantially out beyond the main work surface and beyond the main sterile airflow in order to seek to prevent any inflow or entrainment of contaminants into the sterile zone. Whereas this approach is presented as an improvement on the earlier design, it cuts down on the available surface area of the work surface and 25 access to the work surface in view of the upstanding casing and tall side panels, and there remain risks of entrainment of contaminants due to the horizontal flow of air.

It is an objective of the present invention to provide an improved sterile air trolley that overcomes or mitigates problems of the prior sterile air trolleys, which is 30 compact, efficient, effective and relatively economical to manufacture.

#### Summary of the Invention

According to a first aspect of the present invention there is provided a sterile air 35 trolley comprising a mobile casing having at least one air inlet in its lower region and a plurality of air outlets in its upper region, and enclosing impeller means operative

to move air in through the at least one inlet, through filter means and out of the casing by way of the outlets, the upper region of the casing providing a substantially horizontal work surface, characterised in that the work surface has an upstanding boundary wall extending around its perimeter whereby the work surface and  
5 boundary wall form a tray, the boundary wall being hollow whereby the filtered air is directed into the boundary wall and is emitted through air outlets in the boundary wall facing inwardly over the work surface from opposing sides .

The sterile/filtered air is directed across the work surface from all directions inwardly  
10 of the boundary wall and forms a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall. The continuously replenished rising layer of filtered air prevents any inflow/ entrainment of contaminants into the sterile zone.

15 Compared to the prior configurations of sterile air trolley, the working surface in the apparatus of the present invention is protected by a sterile air layer that is robust while not significantly constricting the available work surface area or impeding access to it.

20 The shape of the tray is suitably rectangular, with the boundary wall defining the four sides of the rectangle and wherein the filtered air is emitted inwardly over the work surface from all four sides.

Particularly preferably the trolley casing is in a modular form having a base unit  
25 housing the impeller and an upper unit comprising the the tray-shaped work surface and boundary wall, the upper unit being readily demountable from and remountable to the base unit. The upper unit may suitably mount to the base unit in a push-fit or friction fit manner or have releasable fastening means. The compact nature of the upper unit enables it to be carried independently of the trolley base unit  
30 and placed in a sterilising facility such as an autoclave, sterilising by steam, radiant energy or other suitable means. Indeed, this opens up the possibility for the work surface of the trolley and the surgical instruments to be sterilised alongside each other to facilitate preparation of the equipment prior to a surgical operation.

35 In a particularly preferred embodiment of the invention, the sterilised surgical instruments are set out on the work surface of the upper unit and sealed in by a film,

foil or lid of barrier material that is mounted above the work surface. A hinged or detachable lid is preferred but a barrier foil may, for example, be stretched over the top of the work surface at the level of the upper edge of the boundary wall and be adhered to the boundary wall by releasable means to enable access to the surgical instruments at the start of the operation.

Preferably the height of the boundary wall is slightly greater than the height of the any of the instruments or other items placed flat on the work surface of the tray in order to fully enshroud those instruments. Furthermore, for a typical surgical tray of approximately 500mm x 700mm in area, it is appropriate to have a minimum height of boundary wall of the order of 90mm. The height limits are suitably measured as the height of the wall that is provided with air outlets.

An optimal maximum height for this area of tray work surface is of the order of 200 to 300mm to maintain the blanket of sterile air without greatly increasing the capacity and power consumption of the impeller.

A preferred rate of flow of air from the outlets is of the order of 0.4 to 0.5 meters per second, and suitable no less than 0.35 meters per second. This lower limit of flow rate is appropriate to prevent the thermal environment surrounding the trolley, including any convection air-flow, from disrupting the air blanket formed over the work surface of the tray. The upper limit helps to restrict entrainment.

Particularly preferably, that part of the boundary wall comprising the air outlets is in the form of a mesh or is densely perforated with many substantially uniformly distributed apertures to provide a substantially uniform flow of air through the boundary wall.

The construction of the part of the boundary wall comprising the outlets is suitably such as to provide a pressure drop of the order of at least 10 pascals and suitably greater than 20 pascals and particularly preferably of the order of 30 – 50 pascals. In one preferred embodiment a mesh providing a 38 pascal drop is used.

According to a second aspect of the present invention there is provided a sterile air cabinet comprising a casing having at least one air inlet in its lower region and a plurality of air outlets in its upper region, and enclosing impeller means operative to

move air in through at least one inlet, through filter means and out of the casing by way of the outlets, the upper region of the casing providing a substantially horizontal work surface, characterised in that the work surface has an upstanding boundary wall extending around its perimeter whereby the work surface and

5 boundary wall form a tray, the boundary wall being hollow whereby the filtered air is directed into the boundary wall and is emitted through air outlets in the boundary wall facing inwardly over the work surface from opposing sides.

According to a further aspect of the present invention there is provided a sterile air

10 tray having a work surface with an upstanding boundary wall extending around its perimeter, the boundary wall being hollow whereby filtered air may be directed into the boundary wall and emitted through air outlets in the boundary wall facing inwardly over the work surface from opposing sides.

15 Brief Description of the Drawings

A preferred embodiment of the present invention will now be more particularly described by way of example with reference to the accompanying drawings, wherein:

20

Figure 1 is a perspective view of a sterile air trolley embodying the invention; and

Figure 2 is a sectional view through the sterile air trolley of Figure 1 taken along a line II-II in Figure 1.

25

Description of the Preferred Embodiment

The illustrated sterile air trolley comprises a mobile casing assembled in two modular parts comprising a base unit 1 and an upper unit 2.

30

The base unit 1 incorporates the fan 3 with its associated impeller 4 to draw air in through an inlet 5 in the casing of the base unit 1. This air is directed upwardly and distributed against the lower face of a filter unit 6 by a manifold 7. The filter unit 6 is a HEPA filter in the form of a rectangular block that spans the hollow interior of the

35 cabinet of the base unit 1 and through which all of the fan driven air must pass, filtering out particulate contaminants in the air.

At the upper end of the casing of the base unit 1, the upper rim 10 of the casing serves as a seat for the upper module 2 of the trolley. A mating lower rim 11 of the upper unit 2 push fits into the upper rim 10 of the base unit 1, providing a fluid tight seal whereby filtered air flowing up through the base unit 1 is directed straight into the interior of the upper unit 2. Releasable clips or clamps (not shown) may be provided to secure the upper unit 2 in place on the base unit 1.

The lower part of the upper unit 2 is formed as a continuation of the cabinet of the base unit 1, suitably having substantially the same cross sectional area of hollow interior and being formed of a sheet metal such as stainless steel. Choice of stainless steel as preferred material for construction at least of the upper unit 2 is to suit the objective of being able to steam sterilise/autoclave the upper unit 2.

As viewed from above or to the side, the upper unit 2 takes the shape of a tray having a floor that serves as a work surface 12 on to which the surgical instruments or other items to be kept in a sterile environment may be placed.

The perimeter of the work surface 12 is bounded by an upstanding boundary wall 13. Since the work surface 12 is rectangular, the boundary wall 13 extends around the four sides of the rectangle.

The boundary wall 13 is hollow and receives air flowing up from the filter unit 6. The lower part of the upper unit 2 serves as a manifold/expansion section to duct the filtered air around the underside of the work surface 12 and up into the wall 13 from all sides. For the avoidance of doubt, although the boundary wall is described as a single continuous hollow wall it can, in principle, be internally partitioned as four separate opposing walls or in any other manner provided that the airflow is not too greatly disrupted and that there is a substantially uniform flow of air out through the wall/walls 13.

The filtered air flows out through a multitude of apertures 14 on the inner face of the wall(s) 13 directing the air inwardly generally toward the centre of the tray. The air flows in from all four sides and rises as a column as the air flows merge. A continuously replenished rising layer/column of filtered air is thus provided within the sterile air zone defined by the boundary wall 13 of the tray shaped upper unit 2.

The inner face of each opposing length of the wall 13 may be formed as a mesh panel and is suitably a stainless steel mesh/grid, the apertures of the grid lattice work each being a respective air outlet 14. The air outlet apertures 14 are 5 substantially uniformly spaced and distributed throughout the extent of each of the opposing lengths of the inner face of the wall 13 to allow substantially uniform airflow over the work surface 12. Any reduction in air flow that would otherwise arise from, for example, the opposing end wall lengths of the boundary wall 13 being farther apart than the side wall lengths of the boundary wall 13, can be 10 compensated for by varying the pressure drop across the wall 13 lengths. As a generality, the mesh is suitably adapted to provide a pressure drop of the order of 38 pascals but this may be adjusted along the lengths of the walls 13 if necessary. The rate of flow of air from the boundary wall 13 inwardly over the work surface 12 is suitably a substantially uniform 0.4m per second.

15

Although not shown in detail, the boundary wall 13 may have the apertured inner face/mesh separately formed from the stainless steel sheet that otherwise defines the boundary wall 13 and with a part of the stainless steel or an additional element forming a frame structure to support the mesh. Conversely, instead of having a 20 grid/mesh, the inner face of the boundary wall 13 may be a continuation of the stainless steel sheet which is perforated in a dense and uniform manner to provide the multitude of air outlets.

25

In the illustrated preferred embodiment the tray form of the upper unit 2 has a rectangular floor area of 500 x 700mm and a boundary wall height of 90 mm. This corresponds to the typical work surface area of a surgical instrument tray/trolley. The surgeon or his assistants have ready access to any surgical implements laid on the work surface 12, the boundary wall 13 does not impede access and yet is of sufficient height to maintain a robust blanket of sterile air over all of the surgical 30 implements placed on the work surface 12.

35

Unlike the prior art, in the preferred embodiment there are suitably no air apertures directed upwardly or outwardly so as to provide sterile air in a broad range beyond the sterile zone. Without any such additional air outlets the arrangement of the present invention functions well and generally better than when any external air outlets are provided.

Although in the illustrated embodiment the tray part of the apparatus is shown as being a rigid construction of fixed wall 13 height, and with the apertures 14 distributed over the full height of the wall 13, in alternative embodiments the outlets 5 14 may be provided for only part of the height of the boundary wall 13 but suitably still to a height of 90 mm with the apertures being predominantly in the upper region of the wall. Accordingly, the full height of the boundary wall may be greater. Additionally, the boundary wall 13 could be adapted to have a telescopic construction to selectively increase or decrease the height of the boundary wall 13 10 so that the height of the wall 13 may be increased when to be used with relatively large bulky tools such as hip operation drills and the like.

The demountability of the upper unit 2 from the base unit 1 provides the user with a great deal of versatility in management of the apparatus. As noted previously, this 15 enables the user, for example, to sterilise the work surface 12 along with the surgical instruments and enables the instruments to be placed ready for use on the work surface 12 and carried with the upper unit 2 back to the base unit 1 for re-assembly of the upper unit 2 to the base unit 1.

20 Although not shown in the illustrated embodiment, the apparatus may be provided with additional air conditioning facilities such as, for example an air cooler or heater. Such facilities, if required, are suitably installed in the base unit 1. The base unit 1 may also be provided with a power transformer or, preferably, a battery for fully independent operation, making the apparatus fully self-contained and mobile.